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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT PAPER NUMBER

3626

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,205

Applicant(s)

ROVINELLI ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-43, 46-48 and 52-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37, 38 and 48 is/are allowed.
- 6) ☒ Claim(s) 23, 25-27, 30-33, 35, 36, 39-43, 46, 47 and 52-66 is/are rejected.
- 7) ☒ Claim(s) 2-21, 24, 28, 29 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. In the amendment filed 12/5/03 in paper number 23, the following has occurred: claims 44, 45, and 49-51 have been canceled, claims 53-66 have been added, and claims 2-5, 13, 16, 18-19, 23-27, 30, 32-34, 37-42, 46-48, and 52 have been amended. Now, claims 2-43, 46-48, and 52-66 are presented for examination.
2. The rejections under 35 U.S.C. 103(a) of claims 2-38, 40, and 48 have been withdrawn by the Examiner based on changes made by Applicants to the claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 23, 25-27, 30-33, 35-36, 40-43, and 53-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The preamble of claim 40 recites a "computer implemented simulation and evaluation method for testing a user's problem solving abilities in response to a complex system." However, there are no recited steps of "testing" or "evaluating" within the body of the claim. Therefore, it is unclear how the body of the claim recites an "evaluation method for testing a user's problem solving abilities."
6. Additionally, claims 23, 25-27, 30-33, 35-36, and 53-66 contain the same deficiencies as claim 40 through dependency and, as such, are rejected for the same reasons as given above. Although claims 2-21, 24, 28-29, and 34 are also either directly or indirectly dependent on claim 40, these claims either individually or through dependency overcome the deficiencies of claim 40 by reciting a step of "evaluating the user."

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7. Claim 41 recites the limitation "the initial patient history state " in line 11. There is insufficient antecedent basis for this limitation in the claim.

8. Claims 42-43 contain the same deficiencies as claim 41 through dependency and, as such, are rejected for the same reasons as given above.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 41-43, 39, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Harless, U.S. Patent No. 5,006,978.

11. As per claim 41, Harless teaches a computer implemented simulation and evaluation method for testing a user's medical problem solving abilities in response to a complex system, said method comprising the steps of: (a) dynamically generating a patient history comprising a patient age, gender, and age of onset of medical condition, extending back in time to a state of normal patient health, wherein the medical condition is one of a plurality of potential medical conditions (see column 4, lines 17-30); (b) receiving at least one intervention input by said user, wherein said at least one intervention includes passive and active interventions (see column 7, lines 56-61); (c) evolving the initial patient history state to a subsequent patient history health state responsive to said at least one intervention (see column 8, lines 61-66); and (d) evaluating said user responsive to said at least one intervention (see column 9, lines 31-35).

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12. As per claim 42, Harless teaches the method of claim 41 as described above, wherein evolving the initial patient history state to said subsequent patient history state occurs over a finite stochastically determined time period (see column 7, lines 61-67).

13. As per claim 43, Harless teaches the method of claim 41 as described above, further comprising the step of repeating said evolving step and receiving step a plurality of times (see column 9, lines 1-7).

14. As per claim 39, Harless teaches a computer implemented simulation and evaluation method simulates interventions to a patient by a user, and evaluates the interventions responsive to predetermined criteria and the interventions, said method comprising the steps of: defining a testing area to evaluate said user responsive to at least one of predetermined and a user profile criterion (see column 10, lines 14-25); selecting genetic information of the patient responsive to said testing area (see column 4, lines 26-30); dynamically generating a patient history responsive to the test area, comprising a patient age, gender, and age of onset of medical condition, extending back in time to a state of normal patient health, wherein the medical condition is one of a plurality of potential medical conditions (see column 4, lines 17-30); receiving at least one intervention input by said user (see column 7, lines 56-61); and evaluating said user responsive to the at least one intervention (see column 9, lines 31-35). Harless does not explicitly teach accessing a profile for said user. Gillo teaches accessing a user profile for a user being evaluated on interaction with a simulated patient (see column 13, lines 36-41). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make such a modification for the purpose of better tailor the testing to the individual test taker.

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15. As per claim 46, Harless teaches a computer implemented simulation and evaluation method for testing a user's medical skills, comprising the steps of: (a) dynamically generating multiple instances of patients (see column 3, lines 28-32), wherein each instance of a patient has an initial patient history state comprising a set of health states, and a patient age, gender, and age of onset of medical condition, wherein the medical condition is one of a plurality of potential medical conditions (see column 4, lines 17-30); (b) evolving at least one of each instance of said patient's initial patient history state to a subsequent patient health state (see column 8, lines 61-66); (c) receiving at least one intervention input by said user, wherein said at least one intervention includes passive and active interventions (see column 7, lines 56-61); and (d) evaluating said user responsive to said at least one intervention (see column 9, lines 31-35).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 47, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harless, U.S. Patent No. 5,006,978 in view of Herren et al., U.S. Patent No. 6,108,635.

18. As per claim 47, Harless teaches a computer implemented method for evaluating a user's response to a simulated patient, said method comprising: selecting subject matter on which to evaluate a user (see column 4, lines 17-25); dynamically generating a medical history for said patient (see column 4, lines 26-30); receiving from the user at least one query pertaining to at least one of a current medical condition and the medical history (see column 7, lines 56-61); evolving the current medical condition forward in time in response to the at least one input

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(see column 8, lines 61-66); and evaluating said user based on the at least one input from the user (see column 9, lines 31-35). Harless does not explicitly teach generating said medical history comprises iterating from a current medical condition backward in time through at least one precursor health state to a normal health state, wherein the medical condition is one of a plurality of potential medical conditions. Herren teaches generating a medical history for a simulated patient by iterating from a medical condition backward in time through at least one precursor health state to a normal health state, wherein the medical condition is one of a plurality of potential medical conditions (see column 7, lines 42-46). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make this modification for the purpose of enhancing the ability to realistically generate histories for the simulated patients presented. Moreover, Herren suggests combining the system with other systems (see column 8, lines 14-17).

19. As per claim 52, Harless teaches a computer simulated method for evaluating the problem solving skills of a user, said method comprising: selecting subject matter on which to evaluate said user from a plurality of subject matter (see column 4, lines 17-25); dynamically generating a first problem environment, wherein said first problem environment is determined by said subject matter (see column 4, lines 26-30); dynamically generating a history of said first problem environment (see column 4, lines 26-30); receiving at least one query including at least one of an intervention and a request for additional information from said user in response to at least one of said first problem environment and the history (see column 7, lines 56-61); receiving medical advice from the user (see column 7, lines 34-42); evolving said first problem environment forward in time in response to the medical advice (see column 8, lines 61-66); and evaluating said user based on said at least one query (see column 9, lines 31-35). Harless

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does not explicitly teach generating said first problem environment comprises iterating from said first problem environment backward in time through at least one precursor situation to an initial situation. Herren teaches generating a medical history for a simulated patient by iterating from a first target health state backward in time through at least one precursor health state to an initial health state (see column 7, lines 42-46). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make this modification for the purpose of enhancing the ability to realistically generate histories for the simulated patients presented. Moreover, Herren suggests combining the system with other systems (see column 8, lines 14-17).

Allowable Subject Matter

20. Claims 37-38 and 48 are allowed. The following is a statement of reasons for the indication of allowable subject matter: The primary reasons for the allowance of claims 37 and 48 is the inclusion of the limitation, in all the claims which is not found in the prior art references, of dynamically generating a patient history, within a patient simulation system, in response to the profile of a user who is being evaluated on the basis of at least one intervention input by the user. While the closest prior art (Harless, U.S. Patent No. 5,006,978) teaches patient simulation and evaluation of the user interactions, it fails to teach such a system that dynamically generates a patient history on the basis of the user's profile.

21. Additionally, the primary reasons for the allowance of claim 38 is the inclusion of the limitation which is not found in the prior art references of dynamically generating a patient history, within a patient simulation system, in response to a test area, which is responsive to the profile of a user who is being evaluated on the basis of at least one intervention input by the

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user. While the closest prior art (Harless, U.S. Patent No. 5,006,978) teaches patient simulation and evaluation of the user interactions, it fails to teach such a system that dynamically generates a patient history on the basis of a test area which is based on the user's profile.

22. Claims 40, 23, 25-27, 30-33, 35-36, and 53-66 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

23. Claims 2-21, 24, 28-29, and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

24. In the remarks filed 12/5/03 in paper number 23, Applicants argue in substance that (1) Harless does not teach utilizing a profile of a user to dynamically generate a patient having a medical history that is tailored to test the user; (2) Harless does not teach that a patient history extends back in time to a state of normal patient health as recited in claim 43; (3) the combination of Harless and Gillio fails to teach certain features of claims 37-40, 2-25, 29, and 34 and 48; (4) the combination of Harless and Fink fails to teach certain features of claims 28, 30-33, 35, and 36; (5) Herren does not teach generating a history by iterating backward in time through a precursor situation to an initial situation as recited in claims 47 and 52; (6) Harless does not teach selecting subject matter on which to evaluate said user from a plurality of subject matter.

25. In response to Applicants' argument (1), the Examiner respectfully submits that the prior art rejections of the claims in which this limitation is present have been withdrawn. Therefore, this argument is moot with respect to the indication of allowable subject matter detailed above.

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Further, it is respectfully submitted that this limitation is not indicated in independent claim 41. In fact, the "dynamic generation" of a patient history is not tied to any particular user's profile or test area. Therefore, the Examiner respectfully submits that, when given the broadest reasonable interpretation to one of ordinary skill in the art, Harless teaches the "dynamic generation" as recited in claim 41.

26. In response to Applicants' argument (2), the Examiner respectfully submits that this limitation is not recited in claim 43. This limitation is also not recited in any of claims 41-43 and 46 to which this argument appears to be directed (see page 23 of Remarks). Therefore, it is unclear to the Examiner what limitations and prior art rejections Applicants are referring to.

27. Applicants' arguments (3) and (4) are now moot in view of the withdrawal of the prior art rejections of these claims.

28. In response to Applicants' argument (5), the Examiner respectfully maintains that the "Patient History Tool" used in conjunction with the "Disease Progression Evaluation Tool," as described in the Herren reference teaches generation of a patient history as claimed in claims 47 and 56. The "Disease Progression Evaluation Tool" models the progression of a disease over a user-specified period of time and, for a "new patient," a patient history is "synthesized from information retrieved from a data and information source (see column 41, lines 30-40 and column 42, lines 2-7). Therefore, the Examiner respectfully submits that, when given the broadest reasonable interpretation to one of ordinary skill in the art, Herren teaches the particular history generation as recited in claims 47 and 52.

29. In response to Applicants' argument (6), The Examiner respectfully submits that the process of actually creating the videodisk, as described by Harless, incorporates a form of selecting subject matter from a plurality of subject matter. In particular, the "program planning and design" and "scripting and content evaluation" (see column 3, lines 54-55) are taken by the

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Examiner to incorporate selection of subject matter from a plurality of subject matter to be included in each video disk.

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Kurzweil teaches a system for dynamically generating a virtual patient for presentation to a user.
- Piemme discloses computer-based simulation models for use in medical training.

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

32. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on Monday-Friday 8am-5:30pm.


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34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CLG
3/5/04



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